

EXHIBIT D

IN RE: Hunt v. Ethicon

THIS DOCUMENT RELATES TO The case of Hunt v. Ethicon

EXPERT REPORT OF DR. LENNOX HOYTE

The following report is provided pursuant to my review of pertinent records for Barbara Hunt. All of the opinions that I offer in this Report I hold to reasonable degree of medical or scientific certainty.

Background

I am a female pelvic surgeon, formally trained in Female Pelvic Medicine and Reconstructive Surgery. My Curriculum Vitae is attached as **Exhibit 1**. I perform about 350 pelvic surgical procedures annually, including robotic, open, and transvaginal procedures to address pelvic organ prolapse, urinary and fecal incontinence, bladder and bowel control problems. About fifty of the surgeries I perform annually are for the removal and/or revision of transvaginally placed mesh, due to chronic complications like mesh related pain, dyspareunia, hyspareunia, erosion, extrusion, exposure, abscess formation, perforation of visceral organs, and bowel and/or bladder dysfunction. From my personal experience with over three thousand female pelvic floor related surgeries, and my experience in training fellows and residents in pelvic surgery, it is my professional medical opinion that pelvic floor surgery is a skill to be painstakingly learned and cannot be universally marketed to all surgeons. I have never been a proponent of trocar-based transvaginally implanted mesh for pelvic organ prolapse repair, and I have never been a proponent of trans-obturator slings for stress urinary incontinence.

Approximately in 2002, when I served as a generalist OB/Gyn physician in Boston, I was approached by an engineer from Johnson and Johnson regarding my research in MR-based 3D pelvic reconstruction. As I recall, the engineer asked if I was interested in building 3D models to help understand the anatomy of the pelvic floor related to pelvic reconstructive surgery. I opted not to follow up on the request, due to my other professional commitments. In the past, I have also attended sponsored cadaver training sessions, and was under consulting contracts with AMS and Bard. In the past 6 years, I have also served as laboratory faculty for 2 cadaver dissection courses, one for Boston Scientific, and the other for Coloplast. I did not teach any transvaginal prolapse mesh placement techniques for either of these laboratory courses. I have also served as a surgical proctor for Intuitive Surgical, also giving lectures and running cadaver lab trainings to teach robotic sacrocolpopexy techniques. I have never taught transvaginal mesh placement techniques for prolapse repair.

The only mesh procedures that I perform are abdominal (open and robotic) sacrocolpopexies, and retropubic slings. I mostly use the Caldera Virtessa Lite Y-mesh for sacrocolpopexy, and the Desara product for retropubic slings. In the past, I have used Bard Pelvitex mesh sheets, as well as the AMS intepro, and Bard Alyte Y-mesh for abdominal sacrocolpopexy. I recall a small number of less than 10 cases where I custom cut the Gynemesh sheet mesh and used it for abdominal sacrocolpopexy. For retropubic sling procedures, in the past, I have used the Bard Uretex and Align retropubic slings, the Boston Scientific Advantage retropubic sling, and the Reemex adjustable sling. On 3 or 4 occasions, I have manually cut and shaped Pelvitex sheet mesh and placed it transvaginally,

anchoring it with sutures to the white line, sacrospinous, and, in one case, Cooper's ligaments. With the exception of the Virtessa Lite Y-mesh and the Desara retropubic sling, I have not used any of the above-named mesh products in over 5 years. I have never placed a kit-based transvaginal mesh for prolapse repair from any manufacturer, in any patient, at any time. I have never been a proponent of trocar-based transvaginally implanted synthetic mesh for pelvic organ prolapse repair or trans-obturator procedures. I currently place retropubic synthetic mesh slings for stress urinary incontinence and have done so for over 10 years. I also perform autologous fascial sacrocolpopexy and retropubic sling procedures, in addition to native tissue repairs. I have never placed a transvaginal synthetic sling in a living patient via the trans-obturator route.

I have reviewed the general and product specific literature related to the Gynecare TVT-Secur product.

I have also personally removed a very large number of transvaginal mesh implants, including Ethicon transobturator slings and mini-slings (TVT-Secur) as well as its Prolift meshes, so determined from patient accounts, surgical operative notes and operating room records. This, together with my substantial training and experience in Engineering, FPMRS, female pelvic surgery, and anatomy, gives me adequate experience to offer opinions about Gynecare TVT-Secur sling complications related to Barbara Hunt.

TVT-Secur Method of Implantation

The Gynecare TVT-Secur is a so-called "single incision" synthetic polypropylene retropubic sling, designed to be placed around the mid-urethra, and anchored in the tissues in the retropubic or pelvic sidewall. Placement is via a midurethral incision, and the

polypropylene is attached to a sharp tip, and is intended to be pushed into the tissues of the retropubic space or the pelvic sidewalls, depending on surgeon preference. Barbed anchors on the ends of the sling are designed to hold the sling in place in the tissues in which they are anchored. According to the IFU, the TVT-Secur sling is supposed to be placed without tension under the mid-urethra. The TVT-Secur mesh arms are designed to scar into place in the periurethral tissues. The ends of the TVT mesh are supposed to remain anchored in the retropubic tissues, such that they scar into place. The midurethral incision is closed over the sling after tension free placement is confirmed, and after cystoscopy demonstrates no sling material in the bladder.

Once implanted, polypropylene is recognized by Ethicon to shrink or contract up to 50%. The same is recognized in the scientific literature. It is also known that inappropriately designed TVT-Secur mesh can result in scar plate formation that is associated with, among others, chronic pain, dyspareunia, urinary dysfunction, inability to remove the device, multiple surgeries to address problems and failure of the device.

Implant Properties

The Gynecare TVT-Secur material is a relatively heavyweight polypropylene mesh, with pore sizes of less than 1 millimeter. This puts the Gynecare TVT sling at increased risk for painful scar plate formation after implantation. I have personally observed this material to deform and curl up when pulled minimally, as it would be during implantation. I have also personally explanted shrunken, curled, deformed Gynecare TVT slings from women like Barbara Hunt with sling complications.

Summary

As a fellowship-trained specialist in Female Pelvic Medicine and Reconstructive Surgery, I have personally treated many women for complications related to transvaginal mesh repairs for pelvic organ prolapse and urinary incontinence. I am familiar with the medical complications that are generally associated with mesh repair surgery, and I am experienced in the recognition, diagnosis and treatment of patients suffering from complications caused by pelvic repair mesh and sling implants. The most common mesh-related complications that I have personally seen are chronic pelvic pain, pain with intercourse, pain with movement, pain with sitting, painful scarring of the vagina and pelvic floor muscles and tissues, painful scar bands or scar plates in the vagina, pain radiating into the groin, buttocks and thighs, paresthesias in the groin, buttocks and thighs, non-healing surgical scars, mesh exposure, mesh erosion into the pelvic organs, vaginal shortening and strictures, chronic inflammation of tissue, wadding or bunching up of the mesh in the vagina, and nerve entrapment. Mesh slings can cause long term complications rarely seen with native tissue repairs.

When I evaluate, diagnose, and treat women with mesh-related complications, I rely on the review of her personally documented history and review of her medical records. I use the information that I obtain from these modalities to determine the cause, treatment plan, and prognosis for the patient's presenting complaint.

Barbara Hunt – Chronology

Patient reported activities prior to Mesh implant:

Bowling	Cleaned house
Roller skating	Washed windows
Long distance walking	Travel
Horseback riding	Full work schedule
Biking	Great sexual relationship with husband.
Boating	

Patient reported activities after Mesh implant:

Only able to walk short distances	Severe abdominal pain
Recurrent infections	Severe vaginal pain
Recurrent incontinence	Intense pain with intercourse

Self-reported history:

2000 – Stress test

2007 – Lumpectomy

Menopause at age 28

15-year smoker - quit in 1991

Relevant Clinical Encounters

1/27/2004 – Procedure Dr. Correnti – Back Surgery
Complaint
 Right-sided Back pain
 Right leg numbness/tingling

Procedure

Right-sided L5-S1 microdiscectomy

11/27/2007 Office Visit (Dr. Waterman)

Complaint

Leaking urine

Constipation

Plan

Refer to Dr. Schwartz or Dr. Harrison

1/16/2008 H+P, pre-procedure (Dr. Schwartz)

History

50-year-old woman with 1-year history of worsening incontinence, requiring up to 5 pads daily. Has involuntary urine loss with coughing, laughing, sneezing, bending, lifting, any degree of exercise including brisk walking.

Testing

Flex cystoscopy & bedside urodynamics

Normal bladder capacity

Moderate bladder neck hypermobility

Moderate urine loss with cough and Valsalva

Allergies

Sulfa, Iodine, IV contrast

Medications

Estrogen supplements

Past Surgical History

Back Surgery

Breast Surgery

Vaginal Hysterectomy at age 24

Medical History

Hearing loss

Back pain

Social history

Denies Alcohol

Denies Tobacco use

Exam

Bladder neck hypermobility

Moderate rectocele

No bladder or adnexal mass

Normal Perineal sensation

Normal rectal tone

Assessment

Worsening stress urinary incontinence in patient

Desires definitive surgical treatment

Plan

TVT-Secur

Reviewed risks, including
vaginal erosion,
recurrent incontinence,
voiding dysfunction

7/16/2008 Procedure #1 (Dr. Schwartz)

Diagnosis

Stress urinary incontinence

Procedure

TVT-Secur

Detail

1cm vertical midurethral incision
Lateral vaginal tunnels developed to 2 cm
TVT-Secur placed into right tunnel and into the obturator internus
TVT-Secur placed into left tunnel in similar fashion
Sling adjusted under urethra without indentation, without redundancy
Extraction suture removed, device rotated and extracted on right and left.
No loosening of the sling noted
Cystoscopy performed
No bladder injury, no sling material noted in bladder

8/23/2012 – Office Visit (Dr. Waterman)

Complaint

Dysuria
Gross hematuria

Exam

Urine dip - 4+ Blood, Nitrites

Plan

Culture sent
Cipro 500 BID x 14 days

9/29/2014 - Phone call (Dr. Draulans)

Complaint

Bleeding, frequency urgency, burning, pressure with urination

Plan

Cipro 500 mg PO BID x 7 days

11/2/2014 - Phone call (Dr. Draulans)

Complaint

Frequency, urgency, painful urination, blood in urine
Patient believes she has a bladder infection and is asking for medication

Plan
Not documented

10/17/2016 - Office Visit (Dr. Draulans)

Complaint

Burning with urination
Hematuria
Back Pain

Exam

Benign

Tests

Urine
2+ Blood
3+ Leukocytes
(-) Nitrites

Diagnosis

Dysuria
Cystitis

Plan

Levofloxacin 500 mg x 7 days

10/19/16 Culture result

10,000 CFU/ml single organism, normal genital flora

10/25/2016 Phone Call (Dr. Draulans)

Complaint

Still has infection, and is out of Levaquin

Plan

Nitrofurantoin 100 mg PO BID x 7 days

10/31/2016 - Office Visit (Dr. Schwartz)

Complaint

Recurrent UTI
Treated by Drs Draulans and Waterman
Gross hematuria, dysuria, frequency, urgency
Urinary incontinence using 3 pads per day
Nocturia 3 x
Feeling of incomplete bladder emptying

Testing

PVR (scan) 15 ml

Urine dip
Negative Ketones, glucose, leukocytes, nitrites, blood

Plan
SUI >> UI, worsening, using 3-4 pads per day.
Worsening
No retention
TVT-SECUR 2008
Trial of Vesicare 5 mg

Recurrent UTI
X6 per year, with gross hematuria
UA Negative today
+ gross hematuria/clots with uti
Start Cranberry supplement
Schedule Renal ultrasound
Schedule Flex cystoscopy

11/14/2016 – Procedure #2 Visit (Dr. Schwartz)

Complaint

Recurrent UTI,
Mixed urinary incontinence
Trial of Vesicare was not helpful
Still having leakage, using 3 pads per day
4X Nocturia
Feeling of incomplete bladder emptying

Test

Urine dip
Negative leukocytes, blood, nitrites

Cystoscopy
Normal, well supported urethra, no trabeculation, no diverticulum
No FB or mesh in bladder or urethra
No SUI with cough or Valsalva

Assessment

Urge and Stress incontinence

Diagnosis/Plan

SUI >> UI, worsening, using 3-4 pads per day.
TVT-SECUR in 2008
No improvement on Vesicare 5 g daily
Increase Vesicare to 10 mg
Caffeine avoidance
Kegel exercises reviewed

Recurrent UTI

X6 per year, with gross hematuria
On Cranberry supplements
Renal ultrasound is WNL

Flex cystoscopy negative
Vaginal erosion of mesh
Noted on exam at left anterior only
Treatment options reviewed
Schedule Sling reversal

12/6/2016 Procedure #3 (Dr. Schwartz)

Diagnosis

Vaginal Mesh Erosion

Procedure

Excision of vaginal mesh (TVT-Secur)

Vaginal Repair

Detail

Left anteriolateral distal mesh exposure noted.
Mucosa incised and mesh dissected out
Mesh excised to medial and lateral margins
Mucosa closed with 2-0 Vicryl figure of 8 sutures
Cystoscopy was performed and no exposed mesh seen in bladder

1/4/2017 – Postop visit from mesh revision procedure, Dr. Schwartz

Symptoms

Incontinence, wearing 4-7 pads per day
Urinary urgency
3x nocturia

Testing

Urine dip
(+) leukocytes
(-) Nitrites, blood, ketones

Plan

Mixed Incontinence
SUI >> UI
Stable
4+ pads/day
TVT-SECUR in 2008
Resume Vesicare 10 mg daily
Caffeine avoidance
Kegel exercises
Recurrent UTI
X6 per year
+ Gross hematuria with clots with UTI
Cranberry supplement
Renal US wnl
Flex cysto negative
Vaginal Erosion of mesh

Mesh erosion excised
Vaginal D/C and bleeding resolved.
No recurrence on exam today
Follow up 12 weeks.

3/1/17 Office Visit (Dr. Schwartz)

Complaint

Urge and Stress incontinence
Nocturia

3/1/2017 – Office visit, Dr. Schwartz

Complaints

Abdominal cramping
On Vesicare 10 mg daily
Still having incontinence
Wearing 4-6 pads per day
3x Nocturia
Urinary urgency

Exam

Atrophic Vagina
No Cystocele or Rectocele

Testing

Urine dip negative for blood, leukocytes, nitrites, Ketones
Bladder scan PVR 32 ml

Plan

Intermittent SP/Pelvic pain
Most consistent with muscle spasm
Possible IC
Diffuse tenderness on exam
On Vesicare 10 mg
Add Myrbetriq 50 mg daily
Caffeine avoidance
Soft tissue pelvic MRI not done
Atrophic Vaginitis
Symptomatic
Start Estrace due to cost
Mixed Incontinence
SUI >> UI
Stable
4+ pads/day
TVT-SECUR in 2008
Caffeine avoidance
Kegel exercises
Recurrent UTI

- None since mesh excision
- Cranberry supplement
- Renal US wnl
- Flex cysto negative
- Vaginal Erosion of mesh
- Mesh erosion excised
- Vaginal D/C and bleeding resolved.
- No recurrence on exam today

3/13/2017 Phone Call (Dr. Syed)

Complaint

Bladder infection, awaiting Rx at CVS

Plan

Patient was asked to come in for evaluation and declined
Stated Macrobid worked in the past and asked for a script for this
Electronic script for Macrobid sent

4/14/2017 – MRI, ordered by Dr. Schwartz

Reason

Chronic pelvic infections

Findings (Abdomen/Pelvis)

Normal kidneys and signal intensity
No abdominal free fluid
Degenerative lumbar disc disease
Likely surgical clips in vaginal cuff
No pelvic masses
Scant sigmoid diverticulosis
Ovaries not visualized
No bony focal lesions

Impression

Unremarkable MRI of pelvis, status post hysterectomy
Scant sigmoid diverticulosis

6/5/2017 – Office visit, Dr. Schwartz

Symptoms

Urinary loss of control
Stress and Urge related
3X Nocturia
Using 4-6 pads per day
Abdominal Cramping
Myrbetriq ineffective

Tests

Urine dip
Negative leukocytes, blood, nitrites

Plan

- Intermittent sp/pelvic pain
 - Most consistent with muscle spasm
 - Possible IC
 - Diffuse tenderness on exam
 - Start Vesicare 10 mg
 - Caffeine avoidance
 - Follow up with GYN promptly
 - Send BMP
- Atrophic Vaginitis
 - Symptomatic
 - Did not use Estrace due to cost
- Mixed Incontinence (as before)
- Recurrent UTI (as before)
- Vaginal mesh erosion (as before)
- Follow up 6 weeks
- BMP drawn

8/14/2017 – Phone encounter, Dr. Schwartz

Complaint

- Patient thinks she has a UTI
- Burning, frequency, urgency
- Back pain, gross hematuria

Plan

- Urinary tract infection
- Urine culture

2/28/2018 – Office visit, Dr. Schwartz

Symptoms

- Urinary loss of control with
 - Cough, sneeze, lifting, bending, urge
- Urinary frequency
- Nocturia
- Atrophic Vaginitis
- Using 5-6 incontinence pads per day
- Brownish-red-pink urine
- Off Vesicare due to cost

Exam

- Bladder scan (pvr)
 - 14 ml
- Urine dip
 - (+) leukocytes
 - (-) Nitrites
 - (-) blood

Plan

- Gross painless hematuria
- Urine culture
- BMP
- CT Abdomen/Pelvis
- Flex cystoscopy
- Pelvic pain
- Off Vesicare 10 mg
- Start Myrbetriq 50 mg daily
- Caffeine avoidance
- Soft tissue pelvic MRI not done
- Atrophic Vaginitis
 - Symptomatic
 - Did not start Estrace due to cost
- Mixed Incontinence
 - SUI >> UI
 - Stable
 - 4+ pads/day
 - TVT-SECUR in 2008
 - Caffeine avoidance
 - Kegel exercises
- Recurrent UTI
 - Single episode mesh excision
 - Treated with abx by MD
 - Cranberry supplement
- Vaginal Erosion of mesh
 - Mesh erosion excised
 - Vaginal D/C and bleeding resolved.
 - No recurrence

4/18/2018 Phone call (Dr. Draulans)

Complaint

- Left lower abdominal pain

4/23/2018 Office Visit (Dr. Draulans)

Complaint

- Abdominal pain, 2 months of LLQ pain
- Sharp, stabbing, short lived.

Exam

- Benign

Tests

- Negative MRI noted

Assessment

- Question colitis versus IBS

Plan

Trial of Levsin

4/18/2018 – Procedure # 4 - Cystoscopy, Dr. Schwartz

Chief Complaint

MD ordered return for cystoscopy

3-4x nocturia

Urinary loss of control cough, sneeze, lift, urge

Using 5-6 incontinence pads per day

Cystoscopy

No trabeculation, no diverticulum, no tumor, no stone,
normal morphology, normally placed ureteric orifices.

Normal cystoscopy

Diagnoses/Plan

Hematuria, gross, painless x several days

Send urine culture

Check BMP (Basic Metabolic panel)

MRI pelvis with/without contrast

Flexible cystoscopy

Intermittent Pelvic pain

Off Vesicare 10 mg

Myrbetriq 50 mg ineffective

Atrophic Vaginitis

Did not start Estrace due to cost

Mixed incontinence

SUI >> UI

Stable

4+ Pads per day

TVT-SECUR in 2008

Caffeine avoidance, start Kegels

Recurrent UTI

Single episode mesh excision

Treated with Abx by primary MD

Cranberry supplement

Vaginal erosion of mesh

Eroded mesh excised

Vaginal D/C and bleeding resolved

No recurrence

Follow up 3 months

9/18/2018 – Office visit, Anna Dunn PA-C (Dr. Schwartz)

Chief Complaint:

Incontinence, mixed

Urinary frequency

3-4 x nocturia

Urgency
Incontinence
Worsening
Going through 3-5 pads per day
Vesicare too expensive
Myrbetriq did not work

Problem list

Gross Hematuria
Urge and Stress incontinence
Nocturia
Atrophic Vaginitis

Medications

Mobic 15 mg
MVI

Allergies

Iodine
Sulfamethoxazole

Social History

Former Smoker x 15 years, quit in 1989

Exam

None

Diagnosis

Urge and Stress incontinence

Plan

Gave Toviaz samples
Discussed other forms of treatment
PTNS
Pelvic floor PT
Offered information on Pelvic Floor PT at Riverwalk
Follow up 4-6 weeks

1/28/2019 Preop clearance (Ashley Miller ARNP, supervised by Dr. Draulans)

Complaint

Preop clearance for sling removal and cystoscopy by Dr. Wyman in Tampa

Exam

Benign

3/14/2019 Procedure #5- sling revision (Dr. Wyman)

Diagnosis

Vaginal foreign body
Recurrent mixed urinary incontinence
Pelvic pain
History of prior TVT sling procedure
Vaginal mesh exposure,

Non mobile urethra
Procedure performed
 Vaginal sling revision/removal
 Urethrolysis
 Cystoscopy
Findings
 Palpable spanning foreign body at mid urethra
 No mesh exposure seen or palpated
 Cystoscopy with no foreign body seen, and normal efflux
Detail
 Midurethral incision made and carried to bladder neck
 Mesh fibers seen in the midline, blue mesh dissected out to the left, right attachment points and transected at bilateral attachment points
 Urethrolysis performed in the standard fashion
 Cystoscopy performed with normal findings
 Mucosa closed with running monofilament sutures.
Pathology
 4 irregular portions of synthetic mesh and blue sutures embedded in fibrous tissue

3/22/2019 – Postop visit (Dr. Wyman)

Subjective

2 weeks out from sling explantation.
Happy with results of her surgery

Exam

Vaginal Mucosa healing well

Plan

Urodynamics at 6 weeks postop, consideration for ARF sling,

5/2/2019 – Procedure #6- (Dr. Wyman)

Diagnosis

Mixed urinary incontinence
Recurrent stress urinary incontinence
Intrinsic sphincter deficiency
History of sling revision/removal

Test Review

Urodynamics showed USUI at low bladder volumes with large leakage
 Low MUCP (9, 11)
 VLPP/CLPP 80-100
 Adequate emptying

Procedure

Placement Autologous Fascial Sling
Cystourethroscopy

Detail

Pfannensteil skin incision
8 centimeters of Rectus Fascia harvested
Tagged in 4 corners with CV2 Gore-Tex
Bladder neck incision, dissected to pubic rami bilaterally
The Space of Retzius was entered bilaterally
Inferior Rectus Fascia dissected up
Long Kelly Clamps were passed from above,
Gore-Tex sling sutures pulled up on left, right
Sling sutures passed thru inferior rectus fascia
Rectus Fascia closed with running loop-Maxxon suture
Cystoscopy performed
No injury noted
Normal efflux bilaterally
Sling sutures tied down over inferior rectus fascia
Sling held loose under the bladder neck during tiedown
Sling tagged to periurethral tissue
Suburethral incision closed
Pfannensteil incision closed in 2 layers

5/17/2019 – Postop visit- (Dr. Wyman)

Complaint

Pain significantly improved since discharge
Some vaginal bleeding and discharge
Changing pads 4-5 times daily.

Exam

PVR 8 ml
Urinalysis
(+) leukocytes
(+) Nitrites

Impression

Vaginal infection
UTI

Plan

Cipro x 7 days
Changed later to Macrobid due to resistant organism to Cipro
Flagyl x 7 days
Follow up at 4 weeks

Post Implantation complaints:

Vaginal bleeding	Recurrent bladder infections requiring
Vaginal pain	repeated antibiotic treatment
Blood in her urine	Urinary frequency/urgency
Pain with intercourse	

Postoperative Pelvic Floor symptoms

Barbara Hunt underwent a Gynecare TVT-Secur sling implantation to treat her stress urinary incontinence in 2008. Following this surgery, she developed vaginal bleeding, vaginal pain, blood in her urine, pain with intercourse, recurrent bladder infections requiring repeated antibiotic treatment, and urinary frequency/urgency. She was evaluated and found to have an erosion of the TVT-Secur sling into her vagina. She underwent resection of the eroded portion of the sling in 2016. Following this partial resection, she continued to have symptoms of urinary urgency, frequency, stress and urge urinary incontinence, blood in her urine, vaginal pain, recurrent bladder infections, and pain with intercourse. She was evaluated with pelvic MR imaging, cystoscopy, and urodynamics, and she was tried on medications to try and stop her urinary urgency, frequency, and nocturia. She had to stop using one of these bladder control medications (Vesicare) due to the high cost. She stopped using the other bladder control medication (Myrbetriq) because it was ineffective in treating her irritative bladder symptoms. She could not afford the vaginal estrogen cream that was offered to treat her vaginal atrophy. After multiple visits to her primary care physician with complaints of recurrent bladder infections, and blood in her urine, she was referred to Dr. Wyman in Tampa, who found

that she had remnants of the TVT-Secur sling in the vagina, and explanted the remaining portions of the TVT-Secur sling in March 2019, with a plan for an autologous fascial sling after the vagina healed. Barbara Hunt's stress incontinence worsened following the explantation of the remaining portions of the Gynecare TVT-Secur sling. She returned to Dr. Wyman for placement of an autologous rectus fascial sling in May 2019. Barbara Hunt's postoperative visit documentation mentioned that she was improved, but no mention is made of her continence status, or of the status of her urinary frequency, urgency, and nocturia. She was diagnosed with a bladder infection at her postoperative visit, and this was adequately treated, with a negative test of cure in June 2019.

In the 11 years after her TVT-Secur sling surgery, Barbara Hunt required five additional surgical interventions to diagnose and address complications caused by the Gynecare TVT-Secur mesh product. The TVT-Secur product failed to cure her stress incontinence, and caused her to develop mixed incontinence, dyspareunia, vaginal pain, recurrent bladder infections, in addition to the vaginal bleeding caused by the erosion of the sling mesh into her vagina. She did not have urge urinary incontinence, recurrent bladder infections, vaginal pain, or pain with sexual intercourse before the TVT-Secur procedure.

Prior to the TVT-Secur implant, Barbara Hunt reported that she and her husband had a great sexual relationship, and she enjoyed bowling, roller skating, long distance walking, and boating, as well as other activities mentioned herein. Following the TVT-Secur implantation, Barbara Hunt reported a nonexistent sex life due to intense pain, and was only able to walk short distances, also due to the vaginal and pelvic pain. Her lifestyle and relationship have been severely affected.

Differential Diagnosis

In determining the cause of a specific injury, the process of “differential diagnosis” is applied to identify potential causes of the injury, and then by process of elimination, to “rule out” the least likely causes to arrive at the most likely cause. This process of differential diagnosis, or differential etiology, is a well-established and universally accepted methodology for determining the cause of injuries employed by physicians throughout the United States. I have used that methodology in arriving at my opinions in this case.

Prior to her Gynecare TVT-Secur surgery, Barbara Hunt had a lumpectomy, and a right-sided microdiscectomy to address right sided back pain and right leg numbness and tingling. None of these pre-existing conditions or surgeries involved the placement of synthetic mesh into the vagina. None of these conditions are recognized as being risk factors for transvaginal mesh erosion. None of these conditions are listed in the IFU as contraindications to use of the TVT-Secur device. Barbara Hunt reported that she smoked cigarettes for 15 years, and quit permanently in 1991, about 17 years prior to her TVT-Secur surgery. Smoking is believed to increase the risk of mesh erosion, but smoking is not listed in the Gynecare TVT-Secur IFU as a contraindication to placement of the Gynecare TVT-Secur products. In addition, there is no literature to suggest that smoking 17 years prior to a mesh sling implant increases chances for an erosion.

Without a mesh implantation, there would be no mesh erosion. This leaves the Gynecare synthetic TVT-Secur as the only cause of the mesh erosion, and vaginal bleeding, requiring multiple surgical mesh excisions. Before the TVT-Secur procedure, Barbara

Hunt did not complain of irritative bladder symptoms, recurrent bladder infections, vaginal pain, and pain with intercourse. These symptoms began after the TVT-Secur implantation. Barbara Hunt was in menopause for many years prior to the implantation of the TVT-Secur product. If her irritative bladder symptoms, vaginal pain, pain with intercourse, and recurrent bladder infections were due to menopausal vaginal atrophy, then they would have manifested long before the TVT-Secur implantation. This leaves the Gynecare synthetic TVT-Secur as the only cause of Barbara Hunt's irritative bladder symptoms, urge incontinence, vaginal pain, pain with intercourse, and recurrent bladder infections.

Barbara Hunt's TVT-Secur implantation was performed using acceptable surgical practice, and in accordance with the IFU. In my opinion, the mesh erosion occurred because of defects in the design of the Gynecare mesh, specifically the heavyweight, small pore material, implanted via a clean-contaminated vaginal environment, which is known to be impossible to completely sterilize.

Mrs. Hunt's complications from her Gynecare TVT-Secur vaginal mesh are similar to complications of other women who have come to me for treatment of eroded Gynecare and other transvaginal mesh systems. In my professional experience, these mesh complications are extremely difficult to treat, and complete removal of the scarred-in mesh represents a significant surgical challenge, which carries risks of substantial blood loss, as well as nerve urinary system damage, and scarring of the vaginal tissues, which causes pain and dyspareunia.

Like Barbara Hunt, many of these affected women require multiple surgical and other therapeutic interventions in order to improve their symptoms to a level that they are able to live with. Despite multiple surgical, medication, and physical therapy interventions,

some of these women will never be cured of their mesh related symptoms.

Opinions:

Barbara Hunt had two reported episodes of erosion of her Gynecare TVT-Secur mesh. Mrs. Hunt's mesh erosion would not have occurred with a native tissue repair like the Burch procedure or the Autologous Rectus Fascial (ARF) sling that she ended up getting from Dr. Wyman in May 2019.

It is my opinion that the surgeons involved in Mrs. Hunt's respective procedures/surgeries (Drs. Schwartz and Wyman), which are referenced above in the chronology, acted reasonably and satisfied the standard of care in their performance of said procedures, respectively. Surgical error did not occur and is not a cause of any of the injuries to Ms. Hunt referenced herein and in her medical records.

In my opinion, the prognosis for her stress urinary incontinence is good, given the placement of the ARF sling. However, the prognosis for her vaginal pain, pain with intercourse, recurrent bladder infections, and urinary urgency, frequency, urge incontinence, and nocturia is uncertain. Assuming that the remaining sling material is completely excised, she might possibly benefit from a course of myofascial release pelvic floor physical therapy, augmented with vaginal estrogen therapy to address her likely atrophic vaginal tissues, possibly improving these symptoms.

If her irritative bladder symptoms persist after physical therapy and estrogen augmentation, she may require treatment with cystoscopic detrusor Botox injections (provided that her postvoid residuals remain in the range seen in her May 2019 postoperative visit), or sacral neuromodulation. Regarding her recurrent bladder infections,

I have seen in my practice that these will resolve after full explantation of the mesh material. If they do not resolve, then she may well need to remain on chronic suppressive therapy for an extended period.

All of my opinions are made to a reasonable degree of medical certainty. I reserve the right to amend or supplement these opinions based on new information, additional facts, or examination findings.

A handwritten signature in black ink, appearing to read 'Lennox Hoyte', written over a horizontal line.

Lennox Hoyte MD, MSEECS

8/15/19